Cosmetics Rules, 1945, for new drug substances discovered in other countries, Phase-I trials were not usually allowed to be initiated in India unless Phase-I data from other countries were available. However, such trials were permitted even in the absence of Phase-I data from other countries if the drug is of special relevance to the health problem of India.

In order to update the requirements of pre-clinical and clinical study norms under Schedule Y at par with international norms and keeping in view the potential, which the country possesses in the field of clinical research, the Drug Technical Advisory Board (DTAB) agreed to undertake the review of Schedule Y. An extensive exercise has been undertaken in consultation with various experts in the field, including ICMR. A draft Notification GSR 694(E) has been published on 28th August, 2003 to invite comments/suggestions from stake holders.

For new drug substances discovered in India, clinical trials may be carried out in India from Phase I through Phase III and data should be submitted as required under item 5, 6 and 7 respectively of Appendix-I.

The Draft Notification provides that — "For new drugs substances discovered in countries other than India, Phase I data required under item 5 of Appendix I, from other country(ies) should be submitted along with the application. After Phase I data generated outside India has been submitted to the Licensing Authority, permission may be granted to repeat Phase I and to conduct Phase I and subsequently Phase III trials concurrently with other global trials for that drug. In all cases Phase III trials must be conducted in India before permission to market the drug in India is granted".

Service negotiations with WTO

*93. SHRIMATI BIMBA RAIKAR : Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

(a) whether India has drawn up an initial offers list for the on-going service negotiations with the WTO;

(b) the areas where offers are being made by India; and

(c) the modes of supply for such services?

THE MINISTER OF COMMERCE AND INDUSTRY (SHRI ARUN JAITLEY): (a) Yes, Sir. India has finalised its initial offer in services in the context of the on-going negotiations under the General Agreement on Trade in Services at the WTO.

(b) and (c) In the initial offer, improvements in the commitments offered in existing sectors as well as introduction of new sectors have been effected. Commitments have been offered in the service sectors of Accounting and Book Keeping, Health, Computer and related services, Telecommunications, Construction and Engineering, Financial, tourism and Travel related services and Maritime Transport services in various modes of supply. The modes of supply in which commitments are offered vary from sector to sector, although overall, all modes are covered. This offer is conditional in nature and binding commitments would eventually be framed after a careful assessment of the counter offers made by other Member countries at the WTO. The elements of the offer are subject to change over the coming months as negotiations in the WTO progress.

Research project on Ayurveda

*94. SHRI VIJAY J. DARDA : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Fifteen medical scientists from USA came in October for a research project on Ayurveda;

(b) if so, whether this research project resulted in opening of new avenues for Ayurveda and other traditional systems of medicine;

(c) the export targets in monetary terms for the year 2004 for traditional medicines; and

(d) whether the country is adequately equipped to effectively show-case the herbal heritage of India to the interested foreign medical professionals?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) and (b) Yes, Sir. Fifteen Medical Scientists from USA came to participate in the Indo-US Workshop on "Traditional Indian System of Medicine Research", jointly organized by the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), (formerly Department of ISM&H), Ministry of Health and Family